

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### The effect of structured education and post-discharge follow-up on the incidence of early complications and mortality after open heart surgery

#### Protocol summary

##### Study aim

The effect of structured education and post-discharge follow-up on the incidence of early complications and mortality after open heart surgery

##### Design

The researcher referred to the research environment (Razi Hospital of Birjand) 100 patients admitted to the ICU of open heart surgery, by non-random and available sampling Will choose. After obtaining informed consent and explaining the research objectives to the research units, these individuals will be randomly divided into two groups of intervention time (structured training and follow-up after discharge) and control (routine training).

##### Settings and conduct

research environment (Razi Hospital of Birjand)  
Intervention group (structured training and follow-up after discharge) and control (routine training)

##### Participants/Inclusion and exclusion criteria

age over 18 years, no history of heart surgery, no history of stroke, no history of complications related to complications, literacy, lack of speech and hearing problems, the possibility of making phone calls, not being part of the health team And not receiving additional training will be.

##### Intervention groups

Educational content, based on the average number of days of hospitalization of these patients will be provided from admission to discharge. After the patient's discharge, a telephone call (with a maximum time of 15 minutes) will be made to follow up. The condition of the patients will be followed up to 3 months after discharge.

##### Main outcome variables

Common and important side effects such as disorders of the central nervous system, cardiovascular system, gastrointestinal, renal, pulmonary, hematologic, infectious, readmission and mortality cases will be investigated. Absolute and relative frequency of these complications will be determined and recorded.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180903040938N2**

Registration date: **2021-01-17, 1399/10/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-17, 1399/10/28**

Update count: **0**

##### Registration date

2021-01-17, 1399/10/28

##### Registrant information

##### Name

Fahimeh Nikraftar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3859 1511

##### Email address

nikraftarf961@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of structured education and post-discharge follow-up on the incidence of early complications and mortality after open heart surgery

#### Public title

The effect of structured education and post-discharge follow-up on the incidence of early complications and mortality after open heart surgery

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age over 18 years Literacy Ability to make phone calls

##### Exclusion criteria:

receive additional training speech and hearing problems

Being a member of a health team history of heart

surgery history of stroke history of disease-related complications

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random time block: In order to prevent patients from contacting each other and exchanging information between them, a random sequence of two-week time blocks will be randomly determined through SPSS software. The sequence is kept in a sealed envelope and when opened every two weeks, it is determined which intervention should be performed.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

##### Placebo

Not used

##### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

##### Street address

ghaffari street

##### City

Birjand

#### Province

South Khorasan

#### Postal code

9۷۱۷۸۵۳۵۷۷

#### Approval date

2020-10-12, 1399/07/21

#### Ethics committee reference number

IR.BUMS.REC.1399.314

## Health conditions studied

### 1

#### Description of health condition studied

open heart surgery

#### ICD-10 code

I23.8

#### ICD-10 code description

Other current complications following acute myocardial infarction

## Primary outcomes

### 1

#### Description

Incidence of complications and mortality

#### Timepoint

At the beginning of the study and 3 months after the intervention

#### Method of measurement

Complication checklist

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Educational content prepared from reputable sources such as Clinical key, Medline plus and nursing consult after approval by experts in this field (nurses and physicians working in open heart surgery) based on the average number of days of hospitalization of these patients in the ward with the titles of initial admission Ward, general rules of the ward, how to wash hands properly, introduction of staff and how to use the nurse summons, the nature of the disease and the cause of hospitalization, methods of diagnosis and treatment of the disease, preparations before open heart surgery, postoperative care Open heart surgery, physical activity, diet, constipation prevention, on-site care, medication regimen and on-the-go training will be provided in each shift from admission to discharge. The presentation method includes lectures, showing pictures and related videos and presenting a pamphlet containing a summary of the content presented in each shift, and after the training, the patient and his caregiver will understand

the training provided with open-ended questions. Also, before presenting each training, the patient's understanding of the training provided in the previous shift will be measured by asking questions and will be reviewed if necessary. After the patient's discharge, a telephone call (with a maximum time of 15 minutes) will be made to follow up on the patient's condition, remind them of the issues mentioned at the time of admission and answer possible questions on a specific day and according to the previously coordinated time with patients / their caregivers. Also, the contact number of the department will be provided to them to answer the questions. The condition of the patients will be followed up (telephone-doctor's visit) up to 3 months after discharge.

**Category**

Rehabilitation

**2****Description**

Control group: Get routine care in the ward

**Category**

Rehabilitation

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Razi Hospital

**Full name of responsible person**

Fahimeh Nikraftar

**Street address**

Ghaffari street, Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3238 1210

**Email**

Nikraftarf1992@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Toba Kazemi

**Street address**

ghaffari street, Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3238 1200

**Email**

drtooba.kazemi@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Birjand University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Fahimeh Nikraftar

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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ghaffari street, Birjand University of Medical Sciences

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**Phone**

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Nikraftarf1992@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Fahimeh Nikraftar

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Instructor

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Master

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**Street address**

Ghaffari street, Birjand University of Medical Sciences

**City**

Birjand

**Province**

South Khorasan

**Postal code**

971783577

**Phone**

+98 56 3238 1210

**Email**

Nikraftarf1992@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Fahimeh Nikraftar

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Participants' information will be kept confidential and the results will be presented without mentioning the names of the individuals.

**When the data will become available and for how long**

After printing the results

**To whom data/document is available**

Everyone

**Under which criteria data/document could be used**

By respecting literary rights and trust

**From where data/document is obtainable**

Birjand University of Medical Sciences

**What processes are involved for a request to access data/document**

After reviewing the application, within a maximum of one week

**Comments**